Talking Points for MERCK Recall of PedvaxHib and Comvax
Key Points:

- MERCK & Company, INC, the vaccine manufacturer http://www.merck.com, has initiated a voluntary recall of two Haemophilus b Conjugate vaccines (Hib Vaccine). This recall is a precaution due to potential contamination of the specific lots for the MERCK brand names PedvaxHIB and COMVAX. No actual contamination has been found in any of the identified lots. Again, this recall is only a precaution. The lot numbers involved in the recall are: PedvaxHIB 0677U, 0820U, 0995U, 1164U, 0259U, 0435U, 0436U, 0437U, 0819U, and 1167U; COMVAX 0376U and 0377U.

- The effectiveness of the vaccine to protect children from disease has not been impacted for these vaccine lots. Individuals who received doses of vaccines from one of the recalled lots do not need to be revaccinated. Individuals who received vaccine from these lots should complete their immunization series with Haemophilus b conjugate-containing vaccine not affected by this recall.

- MERCK recommends that the use of these lots be discontinued immediately. The Indiana State Immunization Program also requests that VFC providers separate VFC vaccine from private stock and complete the Immunization Program's Return Vaccine Form (Provisional) for all recalled doses of Hib vaccine. Also, providers may submit an Immunization Vaccine Order Form requesting replacement doses. Please fax both forms to the State Immunization Program at (317) 233-3719.

- CDC and MERCK have provided clarification regarding the return of the recalled lots of HIB vaccines (PedvaxHIB and COMVAX). As originally stated in the MERCK, Dear Doctor Letter, included in the December 12, 2007 Indiana State Immunization Program's Vaccine E-Letter (#262.5), Stericycle will be sending packets with return instructions to all Indiana VFC providers who received shipments of the affected lots. All VFC providers are asked to follow the instructions and return the vaccine directly to Stericycle as indicated. For specific questions regarding the return process, please contact Stericycle at the following toll-free number, 1-800- 643-0240 or Amy Hord 317.860.1126 or Susan Robinson at 317.605.0932.

- The impact of this vaccine recall on current and future Hib vaccine supply availability is not known. Replacement supplies of PedvaxHIB and COMVAX are minimal. Current supplies of sanofi pasteur's ActHIB is currently limited, but available. The Centers for Disease Control and Prevention http://www.cdc.gov/vaccines has indicated that providers should be prepared for potential Hib vaccine shortages associated with this recall.

- A special edition of the Indiana State Department of Health, Immunization Program's Vaccine E-Letter (# 262.5) was sent via email and fax to all Vaccines For Children (VFC) providers on December 12th. This E-Letter provides detailed information and a list of the affected lots of vaccine and vaccine return information. A second Vaccine E-Letter (#263) was released on 12/14/07, with additional information regarding the recall. Providers receiving the Vaccine E-Letter by fax may have experienced delays in receiving the E-Letter due to Fax transmission limitations.

- Copies of both Vaccine E-Letters may also be obtained online at the Indiana Immunization Program's Children and Hoosiers Immunization Registry Program (CHIRP) https://chirp.in.gov, or the Indiana State Department of Health's Home Page at http://www.in.gov/isdh. All VFC providers are encouraged to go the CHIRP Website for additional important information regarding the HIB vaccine recall. Providers who do not use CHIRP are encouraged to begin a manual review of all vaccine records to identify children who have received the recalled vaccine. A set of Hib Vaccine Recall and Shortage Talking Points are available at the CDC, Vaccines and Immunizations Website: http://www.cdc.gov/vaccines/recs/recalls/hib-recall-parents-faqs-12-12-07.htm

- All VFC providers who received HIB vaccine affected by this recall will be notified by ISDH, Immunization Staff to assist with vaccine returns and required reporting requirements.

- Please report any potentially vaccine-related adverse experiences to your provider and to the Vaccine Adverse Event Reporting System (VAERS) at 1-800-822-7967 (or at www.vaers.hhs.gov), and to Merck at 1-800-672-6372. If you have any questions concerning medical or other issues, please contact the Merck National Service Center at 1-800-672-6372.